

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:

Andrew D. BAROFSKY & Kenton W. GREGORY

Serial No.

08/797,770

Group Art Unit:

3738

Filing Date:

February 7, 1997.

Examiner:

P. Prebilic

For:

METHOD FOR USING TROPOELASTIN AND FOR PRODUCING

TROPOELASTIN BIOMATERIALS

RECEIVED

Assistant Commissioner for Patents Washington, D.C. 20231

TECHNOLOGY CENTER R3700

<u>DECLARATION TO OVERCOME A CITED PUBLICATION</u> (37 C.F.R. 1.131)

I, Cheryl L. Maslen, Ph.D., declare as follows:

- This declaration is to establish completion of the invention in this application in the United States, at a date prior to May 23, 1996, that is the effective date ("Effective Date"), with respect to the above-captioned patent application U.S. Serial No. 08/797,770 ("Application"), of the prior art publication WO 96/14807 to Gregory, et al., that was cited by the Examiner.
- 2. I am an Associate Professor, Molecular & Medical Genetics and Medicine at the Oregon Health & Sciences University ("OHSU") and also Associate Director of the OHSU Heart Research Center, both located in Portland, Oregon.
- I have undertaken tropoelastin research at OHSU in collaboration with Kenton W. Gregory, M.D. and the Oregon Medical Laser Center ("OMLC") in Portland, Oregon.

The work in my laboratory on tropoelastin began on or about September 1995, with the direct participation of Andrew Barofsky, and has been undertaken by Mr. Barofsky, myself, and my laboratory personnel and students.

- 5. The tropoelastin research was performed in my OHSU laboratory substantially continuously during the period of September, 1996 to at least February 7, 1997 and, in fact, this research has continued to the present day, without having been halted or abandoned for other research projects, lack of funding or personnel, or other administrative or financial reasons.
- 6. The tropoelastin research conducted in my OHSU laboratory has been funded entirely by Dr. Gregory at OMLC.
- 7. Dr. Gregory has supervised the tropoelastin research in my laboratory since its inception in 1995, and I have made regular progress reports to Dr. Gregory at OMLC regarding this tropoelastin research. My regular progress reports have been included in reports made by Dr. Gregory and OMLC to the research grant sponsor.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: $\frac{4/25/02}{}$

Cheryl L. Maslen, Ph.D.

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DECLARATION TO OVERCOME A CITED PUBLICATION (37 C.F.R. 1.131)

I, Kenton W. Gregory, M.D., declare as follows:

- 1. This declaration is to establish completion of the invention in this application in the United States, at a date prior to May 23, 1996, that is the effective date ("Effective Date"), with respect to the above-captioned patent application U.S. Serial No. 08/797,770 ("Application"), of the prior art publication WO 96/14807 to Gregory, et al., that was cited by the Examiner.
- 2. I am a co-inventor of the subject matter of the above-referenced patent application.
- 3. Collaborative research was undertaken in Dr. Cheryl Maslen's laboratory at the Oregon Health & Sciences University (OHSU). An initial aim of the collaboration was to develop a tropoelastin expression system to provide quantities of tropoelastin to the Oregon Medical Laser Center (OMLC) for my research there.
- 4. The work in Dr. Maslen's laboratory on tropoelastin began on or about September 1995, with the direct participation of Andrew Barofsky, a co-inventor in the

present patent application, and has been undertaken by Mr. Barofsky, Dr. Maslen and her laboratory personnel and students.

- 5. The tropoelastin research was performed in Dr. Maslen's OHSU laboratory substantially continuously during the period of September, 1996 to at least February 7, 1997 and, in fact, this research has continued to the present day.
- 6. The tropoelastin research conducted in Dr. Maslen's OHSU laboratory has been funded entirely by my research grant for tropoelastin.
- 7. I have supervised the tropoelastin research in Dr. Maslen's laboratory since its inception in 1995, and I have received regular progress reports from Dr. Maslen regarding this tropoelastin research. Her regular progress reports have been included in reports made by me to the research sponsor.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: 6/10/02

Kenton W. Gregory, M.D.